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Nestle HealthCare Nutrition 12 Vreeland Road, 2nd Floor, Box 697 Florham Park, NJ 07932			EXAMINER MAR CETICH, ADAM M	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/701,698

Applicant(s)

BLANK ET AL.

Examiner

ADAM MARCETICH

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 3, 7, 11-20, 22-30 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 7, 11-20, 22-24, 27-30 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. 0226730.0, filed on 18 November 2002 in the United Kingdom has been filed. Therefore, a priority date of 18 November 2002 is given to claims 2,3,7 and 10-36.

35 USC § 112, 6th Paragraph

2. Regarding Applicant's:

- ◆ “first means for threadably attaching” of claims 2, 20, 24 and 29,
- ◆ “third means for fixedly attaching” of claim 2,
- ◆ “attachment means for fixedly attaching” of claims 7, 27 and 28,
- ◆ “first venting means for venting” of claims 7, 10 and 11,
- ◆ “second venting means” of claim 12,
- ◆ “dosing means for controlling” of claim 16,
- ◆ “first rim means” of claims 30, 31 and 33,
- ◆ “second rim means” of claims 30, 32 and 34-36,

3. the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6th paragraph if it meets the following 3-prong analysis:

- (A) The claim limitations must use the phrase “means for” or “step for;”
- (B) the “means for” or “step for” must be modified by functional language;
and
- (C) the phrase “means for” or “step for” must not be modified by sufficient structure,
material or acts for achieving the specified function.

If the examiner finds that a prior art element:

- (A) performs the function specified in the claim,
- (B) is not excluded by any explicit definition provided in the specification for an
equivalent, and
- (C) is an equivalent of the means- (or step-) plus-function limitation,
then the prior art element may be considered by the examiner to be an equivalent to the
means plus function limitation, and the prior art may anticipate the claimed limitation. See
MPEP 2183.

1. Regarding claims 2, 7, 11 and 16, Applicant appears to have met the requirements set forth in MPEP §2181, and Examiner has turned to the specification for clarification.
2. Regarding claims 12, 20, 24 and 27-30 and 33-36, Applicant appears to not meet the requirements set forth in MPEP §2181, because the claims contain sufficient structure, material or acts for achieving the specified function.
3. Regarding claims 2 and 3, the amendments filed 04 January 2010 replace “second means for opening” with “cutting member for opening,” therefore 35 USC § 112, 6th Paragraph is not invoked.

Claim Interpretation

4. Regarding claim 2, the specification provides an enabling description for “first means for threadably attaching” (p. 10, lines 20-29, Figs. 2, 3, internally threaded portion 6). Therefore Examiner interprets the “first means for threadably attaching” broadly to include threaded attachment members.
5. Regarding claim 2, the specification provides an enabling description for “third means for fixedly attaching” (p. 16-17, lines 21-14, Fig. 5, flexible rim 51, recess 52 or thickened portion 55). Therefore Examiner interprets the “third means for fixedly attaching” broadly to include flexible, recessed or thickened portions extending within a packaging system.
6. Regarding claims 2 and 20, the amendments call for a cutting member comprising a center axis that is offset from a center axis of the connector device. Applicant cites the specification for a description of this limitation (p. 11-12, lines 20-13, Fig. 2). However, Fig. 2 depicts cutting means 13 and connector device 1 as sharing the same central axis. In Fig. 2, each of the enteral administration set 3, tube portion 5 and internally threaded portion 6 share the same central axis. Additionally, cutting member 13 is required to open a packaging system upon screwing to a threaded attachment. An off-center cutting member would not operate effectively, since it would be displaced radially while screwing to a packaging system.
7. The only alternative is to form tube portion 5 as off-center from internally threaded portion 6. Fig. 3 shows an embodiment where rigid tube part is offset from internally threaded portion 6. Therefore, examiner interprets amended claims 2 and 20 consistent with the offset rigid tube part 5b in Fig. 3.

Claim Rejections – 35 USC § 103

8. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 2,3,7,11,13,17,19,24,27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Evans; Robert P. (US 2668533), in view of Allanson, Gary R. et al. (US 20030226855). Rationales and arguments are arranged in order of claim dependence.

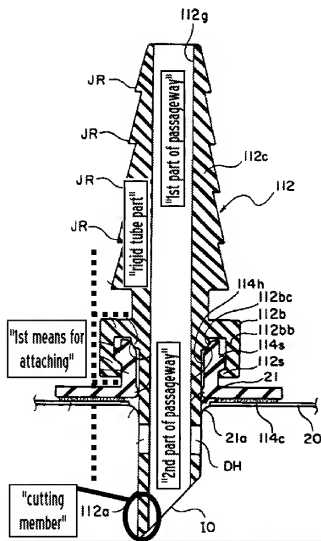
11. Regarding claims 2 and 7, Kawaguchi discloses a connector device for connecting a feeding line of an enteral administration set to a laminated paper packaging system containing a composition (¶ [0027], Figs. 1, 5, adapter body 12 / 112 connecting to pack 20), the connector device comprising:

a rigid tube part being adapted to sealingly attach to the feeding line of the enteral administration set (¶ [0038], Fig. 5, annular ridges JR connecting to tube 30);

the tube part defining a first part of a passageway allowing the flow of the composition contained in the laminated paper packaging system to the feeding line of the enteral administration set (¶ [0057], Fig. 5, upper part of passage 112g connecting to tube 30);

first means for threadably attaching the rigid tube part to the laminated paper packaging system, whereby the connector is screwed to the laminated paper packaging system (¶ [0049], Fig. 5, annular member 112b threadably attaching adapter body 112 to linking member 114 on pack 20);

the first means further defining a second part of the passageway when threadably attached to the laminated paper packaging system (Fig. 5, lower part of passage 112g below annular rim 112b); and



Annotated Fig. 6 of Kawaguchi et al. (US 20040104246)

a cutting member or tubular first spike for opening the laminated paper packaging system upon screwing the connector device onto the laminated paper packaging system (¶ [0049], [0051], Fig. 5, pointed end 112a);

the cutting member protruding from an interior of the first means (annotated Fig. 6, pointed end 112a protrudes

downwards from within the inner perimeter of annular rim 112b).

12. Kawaguchi discloses the invention substantially as claimed, see above. However, Kawaguchi lacks venting means as claimed [2, 7]. Evans discloses a medical liquid dispenser (col. 1, lines 1-5, 30-42, Fig. 1, outlet member 18) comprising:

a first venting means for venting an interior of the laminated paper packaging system (col. 2, lines 45-52, col. 3, lines 47-59, Fig. 2, ball check valve member 56). Evans balances the volumes of dispensed fluid with an equal volume of air. One would be motivated to modify Kawaguchi with the venting means as taught by Evans to restore volume to a laminated package since a partial vacuum will prevent fluid from passing to a patient. That is, if air is not returned to a supply container, the reduced pressure within the container will prevent liquid from flowing effectively. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi as discussed with the venting means as taught by Evans in order to dispense fluid effectively and prevent a vacuum.

Regarding the cutting member center axis offset from a center axis of the connector device, Kawaguchi discloses a connector device and cutting member that share the same center axis. Therefore, Kawaguchi lacks an offset axis as claimed. Evans discloses a connector device having a rigid tube part offset from the center axis of the connector device (col. 2, lines 14-23, Fig. 2, fluid outlet passageway 36 depicted as offset from center axis of outlet member 18). Here, the individual lumens of Evans withdraw fluid or allow air to prevent a vacuum in a fluid source. Evans arranges dual lumens in a connector device to equalize pressure when withdrawing fluid.

13. Kawaguchi in view of Evans discloses the invention substantially as claimed, see above. However, Kawaguchi in view of Evans lacks third means for fixedly attaching, and first and

second rims as claimed [2, 7]. Allanson discloses a connector device (¶ [0008], [0021], Fig. 1, self-sealing dispensing tap), comprising:

a rigid tube part (¶ [0021], Fig. 1, elongate tube 10);

a third means for fixedly attaching a rigid tube part to a laminated paper packaging system (¶ [0038], [0040], Fig. 10, resilient seal 70);

whereby the connector device is secured to an interior surface within the laminated paper packaging system (¶ [0040], Fig. 10, seal 70 pulled through container 100 wall and pressed against interior);

a first rim for fixedly attaching the connector device to the first surface of the laminated paper packaging system upon penetration of the first spike and pressing of the connector device against the first surface of the laminated paper packaging system, the first rim formed of a rigid material (¶ [0038], [0039], Fig. 10, clamp ring 60 threaded to tube 10, suggesting rigid material); and

the first rim located at a fixed first distance from the point of the first spike (Fig. 10, clamp ring 60 distanced from piercing tip 12);

a second rim for said attachment means also fixedly attaching the connector device to an interior surface within said laminated paper packaging system, the second rim formed of a flexible material (¶ [0038], [0040], Fig. 10, resilient seal 70 made of silicone);

the second rim located at a fixed second distance from the point of the spike, the second distance being less than the first distance (Fig. 10, resilient seal 70 between clamp ring 60 and piercing tip 12).

Regarding the limitations of first and second fixed distances, Allanson secures clamp ring 60 with a twisting thread at a fixed first distance. That is, ring 60 remains at a fixed first distance when connected to container 100 (¶ [0040]). Secondly, seal 70 locks at a fixed second distance within reduced diameter section 15 (¶ [0040], [0041], Fig. 10).

Allanson seals the interior of a fluid dispensing system to prevent leaks and provide a hermetic sealing apparatus. With an interior seal, Allanson simultaneously reinforces a seal mechanically against stresses and fluidically against leaks (¶ [0008]). One would be motivated to modify Kawaguchi in view of Evans with the third means for fixedly attaching as taught by Allanson to secure a rigid tube, since each of the immediate invention, Evans and Allanson connect a tapper or spigot to a feeding line. When dangling from a support pole, a feeding line needs to resist tugging forces from a moving patient or from a caregiver repositioning the line.

14. Kawaguchi, Evans and Allanson disclose the invention as substantially claimed, including the first rim means comprising a rigid material of Allanson. However, Allanson does not form clamp ring 50 and tube 10 integrally as claimed [7]. Instead, Allanson forms clamp ring 50 as a separate element (Fig. 10, clamp ring 60 threaded to external threads 16). However, Examiner notes that making a component integral with, as a whole component or as an undivided portion does not in itself provide patentability. Permanently associating an assembly of clamp ring 50 with tube 10 eliminates the step of threading a clamp to a tube, and still allows a flexible silicone seal 70 to enter container wall 100 since silicone seal 70 is flexible and capable of passing by an orifice when deformed with pressure. In other words, an integrally formed assembly of clamp ring 50 and tube 10 allows the connector device of Allanson to be manufactured as a single piece, while eliminating the step for a user to thread clamp ring 50 to

tube 10. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Allanson as discussed by forming clamp ring 50 integrally with tube 10 in order to eliminate steps during both manufacture and use. See MPEP 2144.04(V)(B,C), Making integral and making separable.

15. Regarding claim 24, Kawaguchi discloses a connector device wherein:

the laminated paper packaging system includes a first surface with a frame-like member defining an annular threaded projection (§ [0049], [0050], Fig. 5, linking member 114 attached to pack 20, defining cylindrical component 114a with male threads 14s); and

wherein the first means comprises a threaded annular portion complementary to the threaded projection of the laminated paper packaging system (§ [0050], Fig. 5, annular member 112b threading to cylindrical component 114a).

16. Regarding claim 3, Kawaguchi discloses a cutting member protruding from the connector device in a direction towards the laminated paper packaging system for cutting the laminated paper packaging system upon screwing the connector device onto the laminated paper packaging system (§ [0049], [0051], annotated Fig. 6, pointed end 112a).

17. Regarding claims 13 and 19, Kawaguchi discloses a prefabricated enteral administration system comprising

an enteral administration set (§ [0027], [0032], Figs. 1, 5, tube 30); and

a connector device non-releasably connected to the enteral administration set (§ [0032], Figs. 1, 5, adapter body 112 connecting to tube 30).

Examiner interprets the connection between tube 30 and ridges JR as a “non-releasable” attachment, since a specific amount of force is required to separate the components (§ [0038]). That is, tube 30 and ridges JR will not detach during normal use unless a user pulls the tubes forcefully. Kawaguchi discloses the invention as substantially claimed; see above. However, Kawaguchi lacks a third means for fixedly attaching as claimed. See discussion of claims 2 and 7 above regarding rationale and motivation to modify Kawaguchi in view of Allanson.

18. Regarding claim 17, Kawaguchi discloses an enteral administration kit comprising: an enteral administration set (§ [0027], [0032], Figs. 1, 5, tube 30); and a laminated paper packaging system containing a composition to be enterally administered to a patient (§ [0028], [0049], Fig. 5, pack 20). Examiner cites Allanson to remedy the deficiencies of Kawaguchi, namely a third means for fixedly attaching a rigid tube part. See discussion of claim 2 above regarding rationale and motivation to modify Kawaguchi in view of Allanson.

19. Regarding claim 27, Kawaguchi in view of Evans discloses the invention as substantially claimed, including an adhesive layer of Kawaguchi (§ [0058], Fig. 5, adhesive layer 114c). However, layer 114c of Kawaguchi engages the first surface of a package before a spike penetrates the package. Therefore, Kawaguchi lacks an adhesive layer having the claimed function [claim 27].

Allanson discloses an attachment means comprising a sealing member that engages the first surface of the laminated paper packaging system subsequent to penetration of the first spike (§ [0039], [0041], Fig. 10, clamp ring 60). One would be motivated to modify Kawaguchi, Evans and Allanson by including an adhesive layer as taught by Kawaguchi on clamp ring 60 of

Allanson to attach a connecting member to a package, since the adhesive layer performs the same function of securing a connector member to a package in both cases. That is, Allanson calls for secure sealing between a connecting member and package by including clamp ring 60 on the connecting member.

20. Regarding claim 28, Kawaguchi in view of Evans discloses the invention as substantially claimed, including adhesive layer 114c; see above. However, Kawaguchi in view of Evans lacks a first annular rim as claimed. Allanson discloses a first annular rim (¶ [0039], [0041], Fig. 10, clamp ring 60). See discussion of claim 27 above regarding rationale and motivation to apply an adhesive layer as taught by Kawaguchi to the ring 60 of Allanson.

21. Regarding claim 11, Kawaguchi discloses the invention as substantially claimed. However, Kawaguchi lacks a valve means as claimed. Evans discloses a first venting means comprising a valve means allowing air to enter through the valve means while preventing the composition to be administered to exit (col. 2, lines 45-52, col. 3, lines 47-59, Fig. 2, ball check valve member 56). Evans balances the volumes of dispensed fluid with an equal volume of air. See discussion of claims 2 and 7 above regarding rationale and motivation to modify Kawaguchi in view of Evans.

22. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Evans; Robert P. (US 2668533) in view of Allanson, Gary R. et al. (US 20030226855), further in view of Quinn; David G. et al. (US 4921138).

23. Regarding claim 12, Kawaguchi, Evans and Allanson disclose the invention substantially as claimed, see above. However, Kawaguchi, Evans and Allanson lack a visualization tube and second venting means as claimed. Quinn discloses an enteral fluid dispenser (col. 2, lines 51-55, col. 5, lines 25-34, Fig. 1, fluid dispensing device 24) for connection to a laminated paper package (col. 1, lines 35-39), further comprising:

a visualization tube (col. 5, lines 25-34, Fig. 1, column 26);

one end of the visualization tube being connected to a passageway for the composition to be administered (col. 5, lines 50-55, Fig. 3, spike 58 connecting to lowermost corner 18); and

the other end of the visualization tube being connected to a second venting means (col. 5, lines 25-34, Figs. 1, 3, venting port 32);

the second venting means comprising an air inlet and a second spike adapted to penetrate a second surface of the laminated paper packaging system corresponding to a predetermined fluid level of the composition (col. 5, lines 25-34, 50-55, Figs. 1, 3, venting port 32 in fluid communication with spike 56). Quinn displays the remaining level of nutrient solution (cols. 6-7, lines 64-2) while preventing a vacuum from forming inside a supply package (col. 5, lines 25-34). One would be motivated to modify Kawaguchi, Evans and Allanson with the visualization tube and second venting means as taught by Quinn to display a level of nutrient solution since this prevents solution from being wasted. Kawaguchi calls for conserving nutrient solution by dispensing all remaining fluid (§ [0054], Fig. 7, discharge hole DH dispensing all fluid from container). Showing whether a fluid remains in a supply package prevents it from being wasted. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi, Evans and Allanson as discussed with the

visualization tube and second venting means as taught by Quinn in order to prevent both a vacuum and wasted solution.

24. Claims 14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Evans; Robert P. (US 2668533), in view of Allanson, Gary R. et al. (US 20030226855), further in view of Schafer (US 5993422).

25. Regarding claims 14 and 16, Kawaguchi, Evans and Allanson disclose the invention substantially as claimed, see above. However, Kawaguchi, Evans and Allanson lack a pump unit or dosing means as claimed. Schafer discloses a device for dosing enteral fluids (col. 1, lines 44-47) from a laminated container (col. 4, lines 41-46, Fig. 5, container 29), comprising a pump unit arranged in the feeding line of the enteral administration set. (col. 3, lines 54-59, Fig. 1, pump unit 2). Schafer delivers nutrients at variable rates, independent of the viscosity of a nutrient solution (col. 2, lines 12-16 col. 3, lines 10-16). Additionally, Schafer delivers these nutrients independent of the level of nutrient solution remaining in a container. One would be motivated to modify Kawaguchi, Evans and Allanson with the dosing means as taught by Schafer to deliver solution accurately since a viscous solution may require additional force to dispense it to a patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi, Evans and Allanson as discussed with the dosing pump unit as taught by Schafer in order to dispense viscous solutions at a precise rate.

26. Regarding claim 18, Kawaguchi discloses an enteral administration kit comprising:
an enteral administration set (¶ [0027], [0032], Figs. 1, 5, tube 30); and

a laminated paper packaging system containing a composition to be enterally administered to a patient (§ [0028], [0049], Fig. 5, pack 20). Examiner cites Evans and Allanson to remedy the deficiencies of Kawaguchi. See discussion of claim 2 above regarding rationale and motivation to modify Kawaguchi in view of Evans and Allanson.

27. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Evans; Robert P. (US 2668533), in view of Allanson, Gary R. et al. (US 20030226855), further in view of Broman; Cyrus R. (US 2969063).
28. Regarding claim 15, Kawaguchi, Evans and Allanson disclose the invention substantially as claimed, see above. However, Kawaguchi, Evans and Allanson lack an intermediate bag as claimed. Broman discloses a parenteral fluid set (col. 1, lines 15-19, 63-70, Fig. 1, administration set) comprising a transparent intermediate bag (col. 2, lines 19-26, Fig. 1, device 22 made of translucent PVC). Broman accurately delivers discrete amounts of fluid to a patient by clamping portions of an intermediate bag (cols. 3-4, lines 73-6, 27-29). One would be motivated to modify Kawaguchi, Evans and Allanson with the intermediate bag as taught by Broman to accurately dispense small volumes since a supply package may contain more solution than a patient will consume at a single meal. Additionally, Broman allows a caregiver to record the volumes of solution that a patient consumes. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kawaguchi, Evans and Allanson as discussed with the intermediate bag as taught by Broman in order to dispense fractional amounts of a supply container and accurately record the volumes a patient consumes.

29. Claims 20, 22 and 23 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, Susumu et al. (US 20040104246) in view of Rule; Arthur W. T. (US 4801007) in view of Ninomiya; Satoru et al. (US 5141133), further in view of Evans; Robert P. (US 2668533).

30. Regarding claim 20, Kawaguchi in view of Rule discloses the invention substantially as claimed, including a rigid tube part, first means for threadably attaching, first and second parts of a passageway and cutting member of Kawaguchi. Additionally, pointed end 112a of Kawaguchi protrudes from an interior of a first means as discussed for claim 2 above. Also, pointed end 112a of Kawaguchi is integrally formed with the entire connector device (Fig. 6, pointed end 112a formed as extension of adapter body 112). However, Kawaguchi and Rule lack a cutting member that first cuts the surface only after engagement of the first means of the connector device with a first threaded portion of a packaging system as claimed. Instead, pointed end 112a of Kawaguchi cuts a surface before engagement of a first means.

Ninomiya discloses a pouring plug for piercing a laminated beverage pack (col. 3, lines 28-31, col. 4, lines 13-19, pouring plug for mounting to container wall 18). Ninomiya demonstrates a cutting member that first cuts the surface only after engagement of the first means of the connector device with a first threaded portion of a packaging system (col. 4, lines 6-12, Fig. 3, tubular blade 12 not projecting from lower opening of tubular body 1 after mounting to threaded mounting portion 10). Here, Ninomiya prevents premature rupture of a sealed container (col. 6, lines 44-49, especially lines 56-59). In this rejection, Examiner shortens the lower portion of adapter body 112 of Kawaguchi to allow pointed end 112a to pierce pack 20 only after annular member 112b engages linking member 114. Alternatively, Examiner lengthens

cylindrical component 114a for the same purpose. One would be motivated to modify Kawaguchi and Rule with the dimensions of a cutting member as taught by Ninomiya to prevent premature rupture that would create a leak.

Kawaguchi, Rule and Ninomiya disclose the invention as substantially claimed, but lack a cutting member with an offset center axis. Evans discloses a connector device having a rigid tube part offset from the center axis of the connector device (col. 2, lines 14-23, Fig. 2, fluid outlet passageway 36 depicted as offset from center axis of outlet member 18). See discussion of claim 2 above regarding rationale and motivation to modify Kawaguchi, Rule and Ninomiya in view of Evans.

31. Regarding claims 22 and 23, Kawaguchi discloses a prefabricated enteral administration system comprising:

an enteral administration set and a connector device non-releasably connected to the enteral administration set (§ [0032], Figs. 1, 5, adapter body 112 connecting to tube 30); and a laminated paper packaging system containing a composition to be enterally administered to a patient (§ [0028], [0049], Fig. 5, pack 20).

Kawaguchi discloses the invention substantially as claimed, see above. Examiner cites Rule to remedy the deficiencies of Kawaguchi, namely a first means that also fixedly attaches the rigid tube part to an interior surface of the laminated paper packaging of claim 20.

32. Regarding claim 29, Kawaguchi discloses a connector device wherein:

the first means includes a second threaded portion defined on the connector device (§ [0049], [0050], Fig. 5, cylindrical component 114a having male threads 14s); and

the second threaded portion being complementary to the first threaded portion of the frame-like member of the laminated paper packaging system such that the connector device threadably engages the frame-like member of the laminated paper packaging system (¶ [0050], Fig. 5, annular member 112b threading to cylindrical component 114a).

33. Claims 30 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allanson, Gary R. et al. (US 20030226855).

34. Regarding claim 30, Allanson discloses a connector device (¶ [0008], [0021], Fig. 1, self-sealing dispensing tap), comprising:

a rigid tube part (¶ [0021], Fig. 1, elongate tube 10);

a first end sealingly attachable to a feeding line (¶ [0021], Fig. 1, top of tube 10 capable of attaching to feeding line; also ¶ [0040], “exposed end of tap may be connected to dispensing apparatus tubing”); and

a second end sealingly attachable to a package (¶ [0029], Figs. 1, 3, 10, bottom end of tube 10 for sealing to package 100);

said rigid tube part having at about said second end a first rim means comprising a rigid material (¶ [0038], [0039], Fig. 10, tube 10 having clamp ring 60 threaded, suggesting rigid material); and

a second rim means comprising a flexible material more distal thereon (¶ [0038], [0040], Fig. 10, resilient seal 70 made of silicone);

said rigid tube part having at said second end a spike (¶ [0021], Fig. 1, piercing tip 12);

wherein, upon engagement of said connector device to a top portion of said package, said spike penetrates said top portion of said package (§ [0021], [0029], Fig. 3, piercing tip 12 piercing container 100); and

wherein, upon engagement of said connector device to said top portion of said package, said first rim means engages the outer surface of said top portion of said package (§ [0039], [0041], Fig. 10, clamp ring 60 seated on non-piercing end of tube 10 and placed outside container 100); and

said second rim means engages a corresponding inner surface of said top portion of said package (§ [0040], Fig. 10, seal 70 pulled through container 100 wall and pressed against interior); and

sealingly attaching said connector device to said package between said first and second rim means (Fig. 10, wall of container 100 placed between ring 60 and seal 70, sealing tube 10).

Allanson also discloses an embodiment where the first and second rim means are provided as a single sterile package with pre-positioned components (§ [0041]).

Regarding the limitations of first and second fixed distances, Allanson secures clamp ring 60 with a twisting thread at a fixed first distance. That is, ring 60 remains at a fixed first distance when connected to container 100 (§ [0040]). Secondly, seal 70 locks at a fixed second distance within reduced diameter section 15 (§ [0040], [0041], Fig. 10).

Allanson discloses the invention as substantially claimed, including a first rim means comprising a rigid material. However, Allanson does not form clamp ring 50 and tube 10 integrally as claimed. However, Examiner notes that making a component integral with, as a whole component or as an undivided portion does not in itself provide patentability. See

MPEP2144.04(V)(B,C), Making integral and making separable. See discussion of claims 2 and 7 above regarding rationale and motivation to modify Allanson to have integrally formed first and second rims.

35. Regarding claims 33-36, Allanson discloses a connector device wherein:

said first rim means is a flange (Fig. 10, clamp ring 60 forming flange-shape);

said flange sealingly engaging the outer surface of said top portion of said package upon engagement of said connector device to said package (§ [0039], [0041], Fig. 10, clamp ring 60 sealing outside container 100);

said second rim means is a flexible flange (§ [0038], [0040], Fig. 10, resilient seal 70 made of silicone);

said flexible flange sealingly engaging the inner surface of said top portion of said package upon engagement of said connector device to said package (§ [0040], Fig. 10, seal 70 pressed against interior of container 100); and

said second rim means is a recess portion on said rigid tube part (Fig. 10, resilient seal 70 forming gap for wall of container 100 to fit between ring 60 and seal 70);

said connector device sealingly engaging the inner surface of said top portion of said packaging along said recess portion upon engagement of said connector device to said package (Fig. 10, wall of container 100 placed between ring 60 and seal 70);

said second rim means is a thickened portion on said rigid tube part (Fig. 10, seal 70 extending outwards from tube 10 and therefore forming thickened portion);

said connector device sealingly engaging the inner surface of said top portion of said package along said thickened portion upon engagement of said connector device to said package (¶ [0040], Fig. 10, seal 70 pressed against interior of container 100).

Response to Arguments

36. Applicant's arguments filed 23 June 2010 with respect to the rejection(s) of claim(s) 2,3,7,8,11-19, 24, 27, 28, 30 and 33-36 under 35 USC § 103 over Allanson, Kawaguchi, Rule, Ninomiya, Schafer, Broman, Evans and Quinn have been fully considered and are persuasive. Therefore, the rejection is withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 103 over these cited references.

37. Applicant notes that Kawaguchi lacks a cutting member having an offset axis, and finds that Evans and Allanson fails to remedy this deficiency. Examiner notes that amended claims 2 and 20 call for a cutting member center axis offset from the center axis of a connector device. However, Examiner interprets claims 2 and 20 consistent with Fig. 3 of the drawings, since they show an embodiment having a tubular member offset from the center axis of a cutting member. See claim interpretation above. Evans discloses a fluid outlet passageway 36 offset from center axis of outlet member 18, and equalizes gases when withdrawing fluid from a container.

38. Applicant asserts that Evans and Allanson both lack first means having first and second parts and a cutting member integrally formed with first means that protrudes from an interior of the first means. Examiner instead cites Kawaguchi as teaching the first and second means and

cutting member. Examiner cites Evans as teaching an offset center axis of a connector device, namely fluid outlet passageway 36.

39. Applicant contends that Allanson fails to remedy the deficiencies of Kawaguchi and Evans, namely first and second rims at fixed first and second distances. Applicant notes that the immediate invention is formed by molding, which fixes first and second rims at fixed distances as part of an integral part. Applicant reasons that one would not have been motivated to form the connector of Allanson as an integral part, since it would change the mode of operation. Citing Allanson, Applicant finds that Allanson requires plate 20, seal 30, and lock ring to traverse elongate tube 10 to arrive at final locations along tube 10, and requires moveable pieces that would not function if formed integrally. Examiner instead cites the embodiment of Fig. 10 as teaching clamp 60, and seal 70. In this embodiment, seal 70 folds inward and upward when inserted into container 100. Forming these components integrally would not preclude this operation, since seal 70 can remain attached to tube 10 when inserted.

40. Applicant submits that Quinn, Schafer, Broman and Ninomiya fail to remedy the deficiencies of Kawaguchi, Evans and Allanson. Examiner cites:

- ◆ Quinn as teaching a visualization tube;
- ◆ Schafer as teaching a dosing pump unit;
- ◆ Broman as teaching a transparent intermediate bag;
- ◆ Ninomiya as teaching a cutting member that first cuts the surface only after engagement of the first means of the connector device with a first threaded portion of a packaging system.

41. Applicant notes that each of Kawaguchi, Rule and Ninomiya lack a cutting member having an offset center axis. Examiner cites Evans as teaching an offset connection device in the new grounds of rejection.
42. Applicant reasons that a skilled artisan would not combine Ninomiya with Kawaguchi and Rule, because the cited references are entirely directed to devices having different modes of operation. Applicant finds that since most of the tubular body 1 and a lid 2 of Ninomiya do not enter the container, the skilled artisan would not shorten the bottom pointed end of the elongated pipe adapter body in Kawaguchi or the bottom spike of the tubular teat mounting of Rule in view of Ninomiya because to do so would render the devices of Kawaguchi and Rule inoperable. Examiner notes that this modification of Kawaguchi alters the dimensions of Kawaguchi as given by the example of Ninomiya. Shortening a tube to the extent that it still enters a laminated container does not preclude it from withdrawing liquid from the carton. In other words, modifying Kawaguchi in view of Ninomiya does not preclude Kawaguchi from performing its intended purpose, namely withdrawing fluid from a carton.

Conclusion

43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich
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44. The Examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

46. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761